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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/612,418	07/07/2000	Raymond P. Johnston	54971USA3A.006	8574

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EXAMINER

MARSCHER, ARDIN H

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 02/18/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/612,418

Applicant(s)

Johnston et al.

Examiner

Ardin Marschel

Art Unit

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Oct 15, 2002
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-101 is/are pending in the application.
- 4a) Of the above, claim(s) 10-12, 14-38, 42, 47, 48, 51, 52, 55-59, 62-71, 76, 79-80, and 86-101 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7, 13, 39-41, 43-46, 53, 54, 60, 61, 72-75, 77, and 81-85 is/are rejected.
- 7) ☒ Claim(s) 8, 9, 49, and 50 is/are objected to.
- 8) ☒ Claims 1-101 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

- ☐ Certified copies of the priority documents have been received.
- ☐ Certified copies of the priority documents have been received in Application No. _____.
- ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 17
- ☐ Interview Summary (PTO-413) Paper No(s). _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other:

Applicants' arguments, filed 10/15/02, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 1-7, 13, 39-41, 43-46, 53, 54, 60, 61, 72-75, 77, and 81-85 are rejected under 35 U.S.C. § 102(b) and (e) as being clearly anticipated by any one of the following: Beaver et al. (P/N 4,469,601); Hagen et al. (P/N 4,810,381); or Fitzpatrick et al. (P/N 5,451,504).

This rejection is maintained and reiterated from the previous office action, mailed 7/16/02, as repeated below.

Applicants argue that the instant invention is described in the specification on page 11 as being sheets of films rather than a mass of fibers. In response it is noted that the page 11 citation is clearly therein described as a "Preferred" type of control film of the instant invention. Thus, a reasonable interpretation of the claimed invention is that it should encompass both "Preferred" as well as Non-Preferred embodiments due to the broad wording of the claims which do not negate the presence of fibers. Thus, the claims as worded noting a lack of further limiting definitions for the instant invention practice as a whole in the instant specification is reasonably deemed to include the disclosed inventions of the cited references.

Each of the above listed three U.S. Patents disclose thin layer detection articles or apparatus. Each discloses the presence of a fluid control layer as a fibrous material through which sample solution freely and uninterruptible flows during the performance of the assays practiced with these devices. The samples are spotted onto the various devices and spontaneously wick into the fluid control layer for transport into the device. The fibrous nature of these devices includes a plurality of microchannels therein for fluid flow throughout the devices. These characteristics anticipate the above listed instant claims. Specifically a device as summarized above is depicted in Beaver et al. at Figures 9-14 and described more in detail in the

specification in columns 6-10 therein in a two-dimensional format. The elected specie of an assay reagent in the device is disclosed via the solvent in the strip in column 6, lines 6-29. It is noted that there is no instant limitation as to what is meant by the elected specie as a reagent and thus is reasonably deemed to include any chemical material which mediates or is utilized in the device assay practice and thus also supports reagents as in instant claims 54 and 61 which must operate in solvent. Similarly, Hagen et al. depicts such a fibrous detection article in Figures 1-3 wherein also the detection versus spotting or acquisition zones are clearly shown. Hagen et al. in the specification in columns 4-10 also give details such as coatings. Such coatings as described in column 4, lines 53-65, improve selectivity or transport via polarity alteration which modifies surface energy as required in instant claim 13. Solvent or assay reagent flow is disclosed in column 8, lines 32-66. Lastly, and again similarly, Fitzpatrick et al. depicts an detection article in its sole drawing clearly showing application or acquisition, mobilization, detection, and absorbent zones which also documents the fluid transport uninterrupted throughout the device. Columns 2-11 give more details including solvent assay reagent in column 3, lines 19-26, as required for the elected instant specie. Thus, these disclosures anticipate the above listed instant claims.

Claims 8, 9, 49, and 50 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicants are reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

This application contains claims 10-12, 14-38, 42, 47, 48, 51, 52, 55-59, 62-71, 76, 78-80, and 86-101 drawn to an invention non-elected without traverse in Paper No. 9, filed 10/15/01. A complete response to the final rejection must include cancellation of non-elected claims or other appropriate action (37 C.F.R. § 1.144) M.P.E.P. § 821.01.


Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703)308-4242 or (703)305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ardin Marschel, Ph.D., whose telephone number is (703)308-3894. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (703)308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instrument Examiner, Tina Plunkett, whose telephone number is (703)305-3524 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

February 14, 2003


ARDIN H. MARSCHEL
PRIMARY EXAMINER